PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

Davies Collison Cave
Level 15
1 Nicholson Street
MELBOURNE VIC 3000

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *day/month/year*	30 MAR 2005

TDO FM

Applicant's or agent's file reference	IMPORTANT NOTIFICATION
12381870/TDO/FMT	

International Application No.	International Filing Date	Priority Date
PCT/AU2003/001634	5 December 2003	6 December 2002

Applicant

THE CORPORATION OF THE TRUSTEES OF THE ORDER OF THE SISTERS OFMERCY IN QUEENSLAND et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translations to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide

Name and mailing address of the IPEA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	ALISTAIR BESTOW Telephone No. (02) 6283 2450

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 12381870/TDO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. **PCT/AU2003/001634**	International Filing Date *(day/month/year)* 5 December 2003	Priority Date *(day/month/year)* 6 December 2002

International Patent Classification (IPC) or national classification and IPC

Int. Cl.[7] C12N 015/12; A61P 035/00

Applicant

THE CORPORATION OF THE TRUSTEES OF THE ORDER OF THE SISTERS OFMERCY IN QUEENSLAND et al

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand 6 July 2004	Date of completion of the report 23 March 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer ALISTAIR BESTOW Telephone No. (02) 6283 2450

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU2003/001634

I. Basis of the report

1. With regard to the elements of the international application:*

[X] the international application as originally filed.

[ ] the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of

[ ] the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/fig.

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be nonobvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos: 1, 29 and 37-56 (all partially)

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed. .

☒ no international search report has been established for said claim Nos. **1, 29 and 37 - 56 (partially).**

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-49, 51-56.	YES
	Claims	50.	NO
Inventive step (IS)	Claims	1-39, 43, 45, 49 and 51-54.	YES
	Claims	40-42, 44, 46-48, 50, 55, 56.	NO
Industrial applicability (IA)	Claims	1 – 56.	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The applicant's invention resides in the provision of intergenically spliced DEC-205/DCL-1 mRNA, termed *'DEC-205 SV'* (see page 19, lines 17-22), which encodes the intact DEC-205 ectodomain together with an additional carbohydrate recognition domain, a transmembrane domain and a cytoplasmic domain derived from DCL-1.

Claims 1 and 29 (completely) and 37-38 and 51-54 (partially) are directed towards any DEC-205 intergenic splice variant, and methods of using these splice variants.

Claims 2-28 and 30-36 (completely) and 37-38 and 51-56 (partially) are directed towards DEC-205/DCL-1 splice variants, and methods of using these splice variants.

Claims 55 and 56 (partially) are directed towards methods of using DCL-1.

Claims 39, 41, 45 (completely) and 43, 44, 46-50 (partially) are directed towards agents that modulate the activity of DEC-205 SV, and uses of these agents.

Claims 40, 42 (completely) and 43, 44, 46-50 (partially) are directed towards agents that modulate the activity of DCL-1, and uses of these agents.

The following documents, identified in the International Search Report, as relevant for thepurposes of novelty and inventive step.

D1. Database accession # BAB22377.
D2. Database accession # BAB23242.
D3. Database accession # AAH05501.

Novelty (N)

D1-D3 each disclose peptides that are identical to the DCL-1 peptides of the instant specification. As such, these citations are novelty-destroying for claim 50.

The citations do not anticipate intergenic splice variants of DEC-205/DCL-1, and do not anticipate uses of either DCL-1 or such splice variants. Therefore, claims 1-49 and 51-56 are novel.

Inventive step (IS)

Claims 40-42, 44, 46-48, 55 and 56 differ from D1-D3 in the provision of uses of the DCL-1 peptide in order to modulate DCL-1 activity or to screen for DCL-1. This provision represents routine laboratory experimentation in order to better characterise a newly-identified protein such as that of the citations. Therefore, these claims do not provide an inventive step over the citations.

(Continued on supplemental sheet.)

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Methods of treatment of human beings

Claims 39-45 and 55 recite methods of treatment or diagnosis of human beings. Whilst claims to such matter are acceptable according to Australian law, no unified criteria exist under the PCT. Therefore, if this application should proceed to examination at national phase in one of the PCT contracting states, such claims may not be acceptable under national law.

Descriptive support

Claims 1, 29, 37-38 and 51-54 are not fully supported by the description. The applicant's invention resides in the provision of intergenically spliced DEC-205/DCL-1 mRNA, termed *'DEC-205 SV'* (see page 19, lines 17-22), which encodes the intact DEC-205 ectodomain together with an additional carbohydrate recognition domain, a transmembrane domain and a cytoplasmic domain derived from DCL-1. As such, the applicant is entitled to claims DEC-205 SV and uses thereof. In contrast, these claims are directed towards any DEC-205 intergenic splice variant, and methods of using such splice variants. The specification does not provide an overarching principle whereby any intergenic splice variant of DEC-205 may be identified, it merely provides support for DEC-205/DCL-1 splice variants. Therefore, in the absence of a restriction of the claims to DEC-205 SV splice variants, or uses thereof, these claims lack descriptive support.

Claims 39, 41 and 45-50 are not fully supported by the description. The disclosure of the specification is discussed above. In contrast, these claims are directed towards agents that modulate the activity of DEC-205 SV, and uses of these agents. These are not claims to uses of DEC-205 SV, these are claims to agents that inherently interact with DEC-205 SV, and which owe nothing to the teachings of the specification. Therefore, in the absence of a restriction of the claims to agents when used to interact with DEC-205 SV (ie uses of DEC-205 SV), these claims lack descriptive support.

Claims 40, 42-44, 46-50, 55 and 56 are not fully supported by the description. The disclosure of the specification is discussed above. In contrast, claims 55 and 56 are directed towards methods of using DCL-1, and claims 40, 42-44 and 46-50 are directed towards agents that modulate the activity of DCL-1, and uses of these agents. DCL-1 is an agent that is capable of modulating DEC-2005 SV. However, the claims do not recite such a specific interaction. Thus, in the absence of a limitation of the claims to uses of DCL-1 when used to modulate DEC-205 SV, the claims lack descriptive support.

Claims 1-38, 46-48 and 50-54 lack descriptive support. The disclosure of the specification is discussed above. In contrast, these claims recite derivatives, analogues, chemical equivalents or mimetics of various nucleic acids or proteins comprising DEC-205 splice variants, including DEC-205/DCL-1 splice variants. 'Derivatives', as defined on pages 36 and 37 of the specification, includes any fragment or variant of a molecule, including any number of substitutions, deletions or insertions, with no functional definition. Such derivatives therefore include absolutely any possible nucleotide or amino acid molecule. 'Analogues' are not precisely defined in the specification, but include various modifications as defined on page 37: since the relationship of the analogue to the molecules of the applicant's invention are not precisely defined, this term must be construed in the broadest sense, namely any molecule with any chemical similarity to DEC-205 SV. 'Chemical equivalents' are defined on page 38 as molecules which exhibit any one of the functional activities of the subject molecule: such chemical equivalents therefore include those which share a generic function such as the ability to bind a chelating agent. 'Mimetics' are not specifically defined and so are taken to be molecules that can mimic the activity of the subject molecule, and thus are similarly defined to 'chemical equivalents'. Since none of these recite derivatives, analogues, chemical equivalents or mimetics are in any way limited to the matter of the applicant's invention, namely the provision of DEC-205 SV, either in terms of nucleotide or amino acid sequence or function, these claims are not fully supported by the description.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of V

Inventive step (IS) (continued)

The citations do not suggest intergenic splice variants of DEC-205/DCL-1, and do not suggest the use of such splice variants or the use of DCL-1 to modulate specific cellular activities such as endocytosis, late endosome targetting, intracellular signalling, Hodgkin and Reed-Sternberg cell functioning or antigen presenting cell uptake. Therefore, claims 1-39, 43, 45, 49 and 51-54 involve an inventive step.

Industrial applicability (IA)

The claims meet the requirements of the PCT with regard to industrial applicability.

Non-patent Literature P Category Documents

The following document was identified in the International Search Report.

Kato M et al (2003) Journal of Biological Chemistry 278(36) 34035-34041.

This document was published by the applicants of the instant specification after the priority date of the claims, and discloses the subject matter of the instant specification. This document may become relevant at national phase examination if a priority consideration with the application is identified.